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09/937,706	02/21/2002	Yoav Palticli	PALTIELI=1	5124

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/937,706	Applicant(s) PALTIELI ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-11 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's preliminary amendments filed on 2/21/02 and 3/19/02 have been received. Claims 6 and 12 have been canceled. Claims 16-19 have been added; however, according to 37 CRF 1.126, when claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not). Therefore, claims 16-19 have been renumbered to 14-17 respectively.

2. Claims 1-5, 7-11 and 13-17 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 4, 5, 7-11 and 13-17 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for monoclonal antibodies having accession numbers I-2134, I-2135, I-2136, I-2137 and I-2138, does not reasonably provide enablement for any other monoclonal antibody capable of binding Placental Protein 13 (PP-13). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification fails to disclose how to make and use any other monoclonal antibodies that can bind PP-13 with high affinity nor does it disclose any other monoclonal antibodies with binding characteristics as claimed in claims 4 and 14.

5. Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to provide an adequate written description of the invention and fails to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are: (1) known and readily available to the public; (2) reproducible from the written description; or, (3) deposited in compliance with the criteria set forth in 37 CFR " 1.801-1.809."

The specification lacks complete deposit information for the hybridomas and monoclonal antibodies deposited as I-2134, I-2135, I-2136, I-2137 and I-2138. Because it is not clear that the cell lines possessing the properties of the hybridoma designated I-2134, I-2135, I-2136, I-2137 and I-2138 are known and publicly available or can be reproducibly isolated without undue experimentation, and because the invention of claims 2 and 3 claims or uses the hybridomas and/or monoclonal antibodies produced by those hybridomas, a suitable deposit for patent purposes is required. Accordingly, filing of evidence of the reproducible production of the cell lines and antibodies necessary to practice the instant invention or filing of evidence of deposit is required. Without a publicly available deposit of the above cell lines, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell lines is an unpredictable event. Applicants must comply with the criteria set forth in 37 CFR §§ 1.801-1.809.

If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific cell lines have been deposited under the Budapest

Treaty, that the cell lines will be irrevocably and without restriction or condition released to the public upon the issuance of a patent and that the cell lines will be replaced should they ever become non-viable, would satisfy the deposit requirement made herein.

In the instant case, a statement that the cells lines will be irrevocably and without restriction or condition released to the public upon the issuance of a patent and that the cell lines will be replaced should they ever become non-viable is missing. A viability statement is also missing, i.e. one certifying that the deposit was viable at the time of the deposit or a certificate verifying such from the depository.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit along with the necessary statements in order to meet the criteria se forth in 37 CFR §§ 1.801-1.809. Applicant's attention is directed to In re Lundak, 773 F.2nd. 1216, 227 USPQ 90 (CAFC 1985) and 37 CRF §§ 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 112

6. Claims 1-5, 7-11 and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear how "high affinity" is defined. The specification does not provide a definition so that the metes and bounds of the claim may be determined.

Claims 2 and 3, "A" should be changed to -the—for clarity. Furthermore, the accession number should be used to avoid confusion since the laboratory designations are informal and are unique to each laboratory.

Claim 4, the use parenthetical (One), (Two) and (Three) should be replaced with (a), (b) and (c) for clarity and to provide antecedent support for claims 5, 7 and 8.

Claim 4 is also vague because it is unclear what "conditions" are considered "conducive" to the production of a signal. The recitation of "over a concentration range of 10-500 pg/ml" is confusing. Does this mean that the assay is able to detect PP-13 at a level above 500 pg/ml? Claim 4 also lacks a correlation between detection of signal and the level of PP-13 in the sample.

Claims 5, 7 and 8 "An" should be changed to be -The—for clarity.

Claim 11 and 13-17 "A kit" should be changed to -The kit—for clarity.

Claim 13 is indefinite because it is dependent on canceled claim 12.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4-5, 7, 9-11, 14, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Admon et al (WO 99/38970).

Admon discloses the full amino acid and DNA sequences of placental protein 12 (PP 13) as well as methods and kits using monoclonal antibodies to detect PP 13. See pages 2-4.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Admon in view of Silberman (US 5,198,366).

See the discussion of Admon above. Admon differs from the invention in failing to teach the use of a ligand and a ligand-binding molecule conjugated to the enzyme.

Silberman discloses methods and kits for detecting PP-13 using a first antibody which is attached a solid support, a second antibody bound to the complex form between the first antibody and the PP-13, and a third antibody covalently conjugated to an enzyme as the signal developing system.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assay method taught by Admon using a universal label conjugate such as taught by Silberman because such a labeling system is well known in the art and is a functionally equivalent means of labeling an antigen antibody complex. Furthermore, a label conjugate such as taught by Silberman would provides the advantages of a universal means of label eliminating the needs for specific conjugate for each immunoassay.

Even though Silberman does not specifically disclose the use of biotin and extravidin, such a labeling system is well known and conventional in the art and would have been obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

11. Claims 2 and 3 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fail to teach the hybridoma cell lines and monoclonal antibodies as claimed.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
10/9/03